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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,806	01/25/2002	David Francischelli	M190.135.101	9372

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12/18/2003

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 12/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,806

Applicant(s)

FRANCISCHELLI ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-31 is/are rejected.
- 7) ☒ Claim(s) 12-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2003 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-10, 19, 20 and 22-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Panescu et al ('267).

Panescu et al disclose an electrosurgical system for creating lesions in tissue. The system includes an instrument with an electrode (16), a power source (12) having multiple power settings, a controller (98) for controlling the operating parameters and a source of fluid (50) for cooling the electrode. Panescu et al teach that lesion depth may be controlled empirically or by computer modeling by controlling the power and cooling fluid delivered to an electrode. Tables 1 and 2 (col. 10) show various results of power/cooling combinations and their effect on lesion depth. Columns 9 and 10 discuss the creation of data tables or computer modeling for creating lesion depths. Column 11, lines 5-15 specifically address a controller which is used to input desired lesion depths and identifies a desired power level and treatment time. Column 12, lines 12-25

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specifically discusses that the controller may fix any of a variety of variables to achieve a desired lesion.

Claim Rejections - 35 USC § 103

Claims 1-11, 15 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267).

The Panescu et al device has been addressed previously. In summary, Panescu et al teach that various parameters may be preselected and that one or more of the remaining parameters may then be varied to arrive the desired lesion characteristic (col. 12, lines 12-25). Panescu et al do not expressly state that the desired power setting is selected prior determining the energization time period and that the energization time period is selected prior to the delivery of electrical energy.

The examiner maintains that such a protocol is clearly suggested in the disclosure at column 12 even if it is not expressly stated. The specific order in which the parameters are entered is not particularly important as the remaining variables are adjusted as necessary to arrive at the desired lesion per the "dial-a-lesion" system established by Panescu et al. Furthermore, applicant has not established that there is an unexpected result associated with the particular order in which the parameters are entered, nor does applicant's disclosure establish any specific criticality in the order in which parameters are entered. Like Panescu et al, the applicant's disclosure provides a table, or plurality of tables, for associating various variables (e.g. time, power, cooling) with a desired lesion depth. It is the examiner's continued position that it would be

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obvious to create any number of matrices for the variables to achieve the desired lesion results.

In conclusion, to have utilized the Panescu et al system to first select a power setting and then select a time period for creating a desired lesion in tissue would have been an obvious consideration for one of ordinary skill in the art since Panescu et al clearly suggest that the controller may have input any control variable and automatically adjust the remaining variable(s) to arrive a desired lesion.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al as applied to the claims above, and further in view of the teaching of Mulier et al ('553).

The Panescu et al reference has been addressed previously. There is no explicit disclosure in Panescu et al of drawing the electrode back and forth across tissue to create the desired lesion pattern as part of a MAZE procedure.

Mulier et al disclose an analogous ablation system which includes a catheter with a distal electrode for ablating cardiac tissue. The lesions are to reduce conduction pathways (i.e. MAZE procedure), and Mulier et al teach that it is known to move such catheters across tissue to create the desired lesion pattern. In particular, Mulier et al provide the device with a roller electrode so that it is more smoothly moved across tissue as compared to prior art tip electrodes such as taught by Panescu et al.

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To have moved the Panescu et al device across cardiac tissue to create a desired lesion pattern in tissue would have been an obvious consideration for one of ordinary skill in the art in view of the Mulier et al teaching.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267) in view of the teachings of Jackson et al ('874) and Edwards ('877).

Panescu et al fail to specifically disclose a warning signal to indicate the completion of the lesion procedure.

The examiner maintains that it is generally known in the art to provide electrosurgical systems with warning means (audio and visual) which indicate various operating conditions of the system. In support of this, Jackson et al and Edwards are provided for showing the use of such warning signals. Jackson et al provide an ablation catheter very much like the Panescu et al device which sends a warning signal when an undesirable phase shift occurs (col. 6, lines 3-8), and Edwards discloses a system for creating controllable lesions in tissue and includes a warning means alerting the user of attaining predetermined limits for energy delivery (col. 15, lines 40-50).

To have provided the Panescu et al system with a warning signal means to alert the user of attaining a desired level of treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Jackson et al.

Allowable Subject Matter

Claims 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed November 25 2003 have been fully considered but they are not persuasive.

With regard to the Panescu et al reference and amended claim 1, applicant asserts that Panescu et al describe a physician pre-selecting a targeted ablation time and maximum power and temperature settings and therefore uses a pre-determined or preset time period and therefore cannot anticipate applicant's claim 1. The examiner agrees that Panescu et al do disclose such a system which includes a preset time. However, this is but one example of the Panescu et al system, and the system is not specifically limited to operating in that one mode. Column 12, lines 16-25 expressly state that alternative arrangements are contemplated with any of the various variables being set and any of the remaining variables being varied to produce the desired lesion output. It is the examiner's position that this disclosure is anticipatory of the newly added limitations of claim 1, or that it at least makes obvious these limitations. That is, the language in column 12, lines 16-25 expressly suggests that any of the variables may be chosen to either be preset or variable. This would be inclusive of the steps of first selecting a power setting then selecting a time period, although that specific combination is not expressly set forth. Alternatively, the examiner maintains that it

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would have been obvious to have selected any of the variables in any given order to establish a desired lesion based on this disclosure. Again, applicant's specification is void of any specific criticality associated with the order of selecting the variables and does not set forth any unexpected result obtained by the order in which the variables are selected.

With regard to independent claim 22, applicant asserts that Panescu et al fail to disclose a look table with includes time period information organized as a dependent variable of the power setting an lesion depth. Again, applicant asserts that Panescu et al teach determining power settings based on a predetermined time period. The examiner agrees that one disclosed embodiment of Panescu et al does provide a predetermined time period, but that Panescu et al clearly teach that it is contemplated that any of the parameters may be a dependent variable as disclosed at column 12. Panescu et al does not show the specific table which displays the time as the dependent variable, but it is the examiner's position that it is not necessary for Panescu et al to show every possible combination and permutation of the dependent variables in order to adequately disclose that they are know. The examiner maintains that Panescu et al fairly teach that any of the parameters may be dependent variables and one of ordinary skill in the art would obviously, in not inherently, recognize the alternative combinations of dependent variables which may be provided.

Concerning independent claim 28, applicant continues to assert that the Panescu et al reference fails to disclose an energization time period which is a variable dependent on the power setting and lesion depth. The examiner has addressed this

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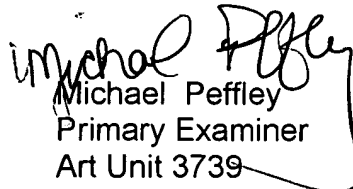
issue and continues to maintain the position that this is fairly suggested in the disclosure at column 12. Moreover, claim 28 does not specifically recite a means or structure supportive of the recited function. Rather, claim 28 merely recites a controller "for electronically selecting a recommended energization time period". The language following the phrase "a controller" is deemed intended use and is not a positive recitation of the structure for performing the recited use. As such, the examiner maintains that Panescu et al clearly teach a controller, and also continues to maintain that the Panescu et al reference does teach that the controller may be used to select a time period as recited in the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
December 12, 2003